

|                                                                                                                            |                                                                                  |                                                     |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D2140220       | <b>(X3) Date Survey Completed</b><br><br>09/25/2026 |
| <b>Name of Provider or Supplier</b><br><br>America's Er Site 002 Llc                                                       | <b>Street Address, City, State</b><br><br>13902 Spring Cypress Road, Cypress, TX |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                                  |                                                     |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D0000              | An announced Validation survey of the laboratory was conducted on 09/25/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| D5429              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>A Based on review of manufacturer instructions, laboratory's instrument maintenance records and staff interview, the laboratory failed to document daily maintenance for seven of seven days maintenance was required on the Medonic M-Series hematology analyzer used by the laboratory in 2025 and 2026. Findings included: 1. Review of manufacturer instructions "Medonic M-Series Maintenance (document 207054D R06. 24.15) revealed: "Daily Maintenance 1. Clean the Open Tube sample probe and Pre-dilute probe using an alcohol wipe. 2. Remove possible traces of salt crystals or blood on the Open Tube probe, probe rinse cup, Pre-dilute probe, and around the top of the CAP Pierce or Autoloader using a paper tissue with a disinfecting solution. 3. Clean outside of the instrument with soft cloth and DI water if needed." 2. Review of laboratory's instrument maintenance records revealed the laboratory documented on the "Daily Shift Duties" log only the "Medonic/Pathfast Wipe Down". There was no documentation of the "Medonic/Pathfast Wipe Down" for the following days: 02/19 /2025 04/20/2025 04/27/2025 06/21/2025 06/13/2026 06/20/2026 06/28/2026 3. In an interview on 09/25/2026 at 1150 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. B Based on review of manufacturer instructions, laboratory's instrument maintenance records and staff interview, the laboratory failed to document weekly</p> |

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | <p>maintenance for twelve of twelve instances maintenance and replacement of the Tip Waste Box was required on the Pathfast chemistry analyzer from May through July 2026. Findings included: 1. Review of manufacturer instructions in the "PATHFAST Operator's Manual Ver. 4.00US" revealed: "13.1.1 Weekly maintenance 1) Replacing the Tip Waste Box Replace it every 20 batch runs or once a week, whichever comes first. 2) Cleaning the reagent Cartridge Rack ... 3) Cleaning the stage surface ... 13.1.2 Monthly maintenance Perform the following monthly. 1) Clean the outside of the instrument ... 2) Cleaning the piercing nozzle edges ... 3) Cleaning the Tip Holder ..."</p> <p>2. Review of laboratory's instrument maintenance records for the twelve weeks from May through July 2026 revealed the laboratory documented on the "Daily Shift Duties" log only the "Medonic/Pathfast Wipe Down", which did not specify individual components of the above weekly/monthly required maintenance and did not address replacing the Tip Waste Box every 20 batch runs or once a week, whichever comes first. 3. In an interview on 09/25/2026 at 1240 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>D5445</b> | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory's submitted Form CMS 116, quality control (QC) records, Individualized Quality Control Plan (IQCP) establishment studies and staff interview, the laboratory failed to document IQCP establishment study QC every eight hours for i-STAT CG4 (measuring pH, partial pressure of oxygen [PO2], partial pressure of carbon dioxide [PCO2], and lactate), i-STAT PT/INR (measuring prothrombin time [PT] and International Normalized Ratio [INR]) and Pathfast D-Dimer, three of three test platforms used by the laboratory in 2025 and 2026 that required QC every eight hours. Findings included: 1. Review of laboratory's submitted Form CMS 116 revealed the laboratory was in continuous twenty-four hours operation, every day of the week. 2. Review of laboratory's 2025/2026 QC records revealed the i-STAT CG4, i-STAT PT/INR and the Pathfast D-dimer had QC performed once per month, or at minimum every thirty-one days. 3. Review of IQCP establishments for the i-STAT CG4, i-STAT PT/INR and Pathfast D-Dimer revealed the studies' QC data was collected once per day for thirty-one days instead of every eight hours. 4. In an interview on 09/25/2026 at 1230 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.</p> |
| <b>D6005</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(c)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:

Based on review of laboratory's records, policies and staff interview, the laboratory failed to document Laboratory Director's onsite visits every 6 months with evidence of performing laboratory director's duties for at least three of three visits required from January 2025 to August 2026. Findings included: 1. Review of laboratory's records revealed there was no documentation/evidence of Laboratory Director's onsite required visits every 6 months from January 2025 to August 2026. 2. Review of laboratory's policies revealed there were no protocols in place requiring Laboratory Director's onsite visits at least every 6 months. 3. In an interview on 09/25/2026 at 1230 hours in the conference room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.